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Health regulations governing fish processing plants and fish and aquaculture products for human consumption

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OFFICE OF THE PRESIDENT

18430 Royal Decree 1521/1984 of 1 August 1984 approving health regulations for fish processing plants and fish and aquiculture products for human consumption.

It is necessary to change and adapt the Health Regulations governing fish products for human consumption approved under Royal Decree 1521/1977 of 3 May 1977 to reflect current market requirements.

Based on a mandatory report from the Inter-Ministerial Food Regulatory Committee and on the recommendation of the Minister of Economic Affairs and Finance, the Minister of Industry and Energy, the Minister of Agriculture, Fisheries and Food and the Minister of Health and Consumer Affairs, and after discussion by the Council of Ministers at its meeting of 1 August 1984,

I HEREBY DECREE THAT

Sole Article

The attached Health Regulations governing fish processing plants and fish and aquiculture products for human consumption are approved.

TEMPORARY PROVISIONS

One

The changes and adaptations that must be made to installations as a result of the new requirements contained in these Regulations are to be made within twenty-four months counting from the date on which this Royal Decree comes into force.

This requirement does not apply to the technical conditions stipulated in Article 6 (6), which, since they are difficult to incorporate into installations currently in operation, will only be compulsory for plants and vessels constructed after the date on which this Royal Decree comes into force.

Two

Article 19 of these Health Regulations will not become compulsory until the dates stipulated in the temporary provisions of Royal Decree 1058/1982 of 12 August 1982 which approves the general regulations governing labelling, presentation and advertising of packaged food products.

Three

Until the dates mentioned in temporary provision two, Article 20 (labelling) of the Health Regulations for Fish Products for Human Consumption approved under Royal Decree 1521/1977 of 3 May 1977 will remain in effect.

Four

Counting from the date on which this Royal Decree containing the authorized list of additives is published in the Official Gazette, a period of three months is allowed for all the packaged products covered by these Regulations which contain such substances to adapt their labelling to the contents of the list in question [sic].

FINAL PROVISIONS

One

Royal Decree 1521/1977 of 3 May 1977 approving the Health Regulations for Fish Products for Human Consumption is revoked on the date on which this Royal Decree comes into effect, as are all regulations of equal or inferior force that are contrary to the provisions of this Royal Decree, with the exception mentioned in Temporary Provision Three.

Two

The competent ministries are authorized to issue the regulations necessary to complete, develop and better comply with the provisions of the attached Health Regulations, contingent on mandatory prior reports by the Inter-Ministerial Food Regulatory Committee.

Given in Palma de Mallora on 1 August 1984

King Juan Carlos

Javier Moscoso del Prado y Munoz
Minister of the Office of the Presidency

HEALTH REGULATIONS GOVERNING FISH PROCESSING PLANTS AND FISH AND AQUICULTURE PRODUCTS FOR HUMAN CONSUMPTION

PRELIMINARY CHAPTER

Sphere of Application

Article 1

The intent of these Regulations is to define for legal purposes what is understood by fish products and to set standards for handling, preparing, preserving, transporting and marketing them, and in general, to regulate them under the law.

These Regulations are binding on establishments engaged in handling, preparing, preserving, processing, storing, marketing and transporting (by land, air, sea or inland waterway) fish products and are equally binding on importers of such products.

Handlers and processors of fish products are defined as those private and corporate persons who, in use of permits issued by competent official bodies, engage in obtaining, handling, preserving, preparing, processing, marketing or transporting the products defined in Articles 2, 3 and 4 of these Regulations, both at sea and on land.

CHAPTER ONE

Definitions

Article 2 Products governed by these Regulations

1. Fish Products. Fish products are defined as each and every one of the edible species of saltwater and freshwater fish, shellfish and cephalopods, be they whole, parts or pieces thereof.

1.1 Fish. The edible saltwater and freshwater animals, whose official vernacular and scientific names are given in Chapter XII, 3.12.02 of the Spanish Food Code. Upon receipt of an assenting report from the Inter-Ministerial Food Regulatory Committee, the competent

departments may make pertinent changes to the specific nomenclature in question.

1.1.1 Live Fish. Cold-blooded vertebrates; Pisces, Chondrichthyes, Cylostomi.

1.1.2 Mammals

1.1.3 Invertebrates and batracian amphibians.

1.2 Shellfish. Edible saltwater and freshwater invertebrates (crustaceans, non-cephalopod Mollusca and echinoderms, whose vernacular and scientific names are given in Chapter XIII, 3.13.02 of the Spanish Food Code. Upon receipt of an assenting report from the Inter-Ministerial Food Regulatory Committee, the competent departments may make pertinent changes to the specific nomenclature in question.

1.3 Cephalopoda (Xiphonopoda). Edible saltwater and freshwater invertebrates whose vernacular and scientific names are given in Chapter XIII, 3.13.02 of the Spanish Food Code. Upon receipt of an assenting report from the Inter-Ministerial Food Regulatory Committee, the competent departments may make pertinent changes to the specific nomenclature in question.

2. Aquiculture products. Products obtained by cultivating species of fish in fish farms, fish ponds and continental waters.

Article 3 Forms of presentation, preservation and sale of fish and aquiculture products

1. Fresh products. Those that have not been subject after they have been caught to any preservation process. Bleeding, heading, gutting, the use of ice with or without salt, or placing in cold storage are not considered to be preservation processes. Food additives authorized by the Under Secretary of Health and Consumer Affairs, upon receipt of an assenting report from the Inter-Ministerial Food Regulatory Committee, may be used to prevent melanosis in crustaceans.

2. Frozen products. Those which, in their fresh state, have been subject to the action of cold until the temperature in the centre of the product has dropped to the point specified in Article 12 (3) of these Regulations over a maximum time of 8 hours, except for products treated with brine. "Flashfrozen" products are those belonging to the "extra" grade described in Article 23 (6) which rapidly reach the maximum crystallization zone, with the temperature in the centre of the product dropping from 0°C to -5°C in less than two hours.

Products frozen in this way must be kept in freezers until they have stabilized thermally. Cold storage installations must be kept at temperatures that guarantee this stabilization but such installations may not be used for initial freezing purposes.

3. Green salted products. Subjected to the action of common salt, in solid or diluted form.

4. Salted products. Subjected to the prolonged action of common salt, in solid or diluted form, which may or may not contain other condiments or spices.

5. Smoked products. Those which, previously salted or not, are subjected to the action of wood smoke or other authorized procedures.

6. Dried products. Subjected to the action of dry air or any other authorized procedure until their moisture content is below 15%.

7. Dried salted products. Subjected to the action of common salt and dry air until their moisture content is not above 50%.

8. Cooked products. Those subjected to the action of steam or boiling water or any other authorized system, alone, or with the addition of common salt, condiments, spices or food additives authorized by the Under Secretary of Health and Consumer Affairs, after receipt of an assenting report from the Inter-Ministerial Food Regulatory Committee.

9. Semi-preserved products. Although broadly speaking the products defined in points (3) to (8) can be considered semi-preserves, for the purposes of these Regulations semi-preserved products are defined as those which, with or without the addition of other authorized food substances, have been stabilized for a limited time using an appropriate treatment and are kept in waterproof containers under normal pressure.

10. Canned products. Those which, with or without the addition of other authorized food substances, have been placed in hermetically sealed containers and have afterwards been treated using appropriate physical procedures to ensure that they can be stored as non-perishable products.

11. Dismembered products ["productos despiezados"]. Fish that have been dismembered, which consists of separating the different parts of the fish following anatomical criteria so as to obtain commercial products. The products obtained must always retain a typical anatomical shape.

12. Pieces. Products that have been cut up, which consists of obtaining pieces from a whole product or its dismembered parts, following conventional criteria.

In all instances, the pieces must have an anatomically identifiable structure.

13. Minced products. Those minced to obtain small pieces from the whole product, its larger parts or pieces. These small pieces must have a typical tissue structure.

14. Paste products. Those composed of finely-ground pieces of one or more species of fish products, parts or pieces.

15. Dehydrated or lyophilized products. Whole or cut up products whose water content has been reduced to a maximum of 5%, following authorized methods, which must be vacuum packed or packed with inert gas.

16. Fish sausage. Fish sausage is made from skinless fish and retains its tissue structure.

17. Block of pressed fish products. Prepared from skinless fish fillets or crumbs, pressed so as to remove fissures or interstitial spaces; the surfaces are smooth and homogeneous, the edges clearly defined.

Article 4 Fish parts

1. Fins. The fleshy appendages located on the dorsal line or the lateral sides of the bodies of Cephalpoda, Decapoda and Chondrichthyes.

2. Claws or legs. The locomotive appendages, pincers or claws of crustaceans.

3. Tentacles. The tentacles of cephalopods.

4. Head. The anterior part of the bodies of fish, sectioned at the level of the occipital bone and the first cervical vertebra.

5. Meat. The soft parts of bivalve mollusks and gasteropods.

6. Tail. In the case of fish, the product obtained by cutting perpendicular to the spinal column in the distal caudal part of the body. Always attached to the corresponding section of the spine. For crustaceans, the abdomen or pleon, obtained by separation from the animal's cephalothorax.

7. Rings and crowns. Perpendicular cuts made in the mantle of cephalopods.

8. Flanks or bellies, fins or collars. The muscular masses delimiting the abdominal cavity of fish.

9. Fillets. The muscular masses of fish, irregular in dimension and typical in shape, removed from the body by cutting parallel to the spine.

10. Roe. The ovaries of female fish covered with collenchyme, with the oviducts and part of the uterus.

11. Eggs. The unfertilized gametes obtained from the females of fish and crustaceans.

12. Back. The muscular masses of the dorsal part of fish.

13. Steaks. The products obtained by cutting perpendicularly or transversally to the spine, with smooth surfaces and of different thicknesses; the corresponding section of the spine is always included. For cephalopods (decapods), rounds may be accompanied by the corresponding tentacles.

14. Tubes, sheathes or flat sections. The mantle or body of decapod cephalopods, with the fins, legs, heads and viscera removed. The distal portion of the sheath may be sectioned.

15. Crumbs. Small portions that conserve the muscular tissue structure of fish products.

16. Cheeks and tongues. The muscular masses, covered with skin and mucus, between the two extremes of the lower jaw of fishes.

Article 5 Establishments governed by these Regulations

1. Fish wholesale exchanges. Centres where fish are contracted, handled and sold for the first time.

2. Fresh fish preparation rooms. Installations on land engaged in sorting, dismembering, filleting and packaging fresh fish for sale.

3. Frozen fish preparation rooms. Installations engaged in sorting, dismembering, filleting and packaging frozen fish for sale. They may also prepare pressed blocks of these products.

4. Shellfish stations. Stations communicating with the sea or fed with seawater engaged in maintaining live crustaceans for commercial purposes.

5. Depuration stations. Establishments equipped with the installations required to eliminate pathogens from live mollusks for human consumption immediately prior to packaging at the station itself.

6. Crab cleaning and handling centres. Installations to clean and purify crabs by immersion in clean running water.

7. Fish cooking plants. Plants engaged in cooking fish products by steam, boiling water or any other authorized system, for supplies to processing industries, institutions, central markets and retailers.

8. Central markets. Centres for collecting and handling fish products for the purpose of wholesale marketing and sale.

9. Refrigerated storage. Installations for maintaining and preserving fish products through the action of cold.

10. Freezing plants. Plants possessing suitable freezing systems.

11. Retail fish outlets. Duly equipped establishments for handling fish products for the purpose of retail marketing and sale.

12. Salting and curing plants. Plants engaged in treating the fish products defined in Article 3 (3) (4) and (7).

13. Smoked fish plants. Plants engaged in treating fish products by the action of salt and smoke.

14. Semi-preserve and canning plants. Plants equipped to prepare the products defined in Article 3 (9) and (10).

15. Fish-breeding and finishing establishmnents. Installations engaged in breeding and/or finishing deep sea and continental fish and shellfish.

CHAPTER II

GENERAL CHARACTERISTICS AND CONDITIONS FOR VESSELS AND PLANTS

Article 6

The industrial installations of all the establishments governed by these Regulations must be built to designs or plans that guarantee proper technical and hygienic treatment of raw materials, products and byproducts, facilitating proper application of the different manufacturing processes to ensure public health.

Accordingly, vessels and plants that prepare fish products must compulsorily comply with the following requirements.

1. Buildings and premises must be appropriate for the use to which they are put, and be suitably located and orientated. They must be of adequate size, easily accessible, located at a suitable distance from any source of dirt, contamination or pollution, and be kept strictly separate from houses and premises where any person sleeps or prepares food. Plant buildings and surrounding zones must be kept free from disagreeable odours, smoke, dust and other contaminating elements.

Both vessels and industries must be well built, and appropriate materials that pose no risk whatsoever of causing poisoning or contamination must be used in constructing and repairing them. They must be easy to clean, and insects, birds, rodents and other animals must be prevented from entering.

2. Floors in working areas where fish products (including waste) are received, handled, prepared, packaged or stored must be built from non-absorbent, resistant materials, unaffected by the acids or alkalaies used to clean them. They must be easy to clean and slope towards drains to permit water to run off.

Drains must be of adequate size and fitted with metal grids, hydraulic seals and/or safeguards to prevent odours from backing up and stop rodents from entering.

3. The walls of work areas must be smooth, non-absorbent, light in colour and completely covered with a material or paint that allows for washing without causing deterioration. They must not have interior hollows where insects or rodents can nest.

4. The ceilings must be built so as prevent dust or condensation from accumulating, allow for easy cleaning and always be kept in a condition in which they cannot contaminate products.

In newly-built installations, the joints between floors and walls and between walls and ceilings must be rounded to facilitate cleaning.

5. In plant handling and processing areas, all the doors giving access to fish products must be sufficiently wide, sturdily built, and close automatically. Doors between the different areas in which fish products are handled, prepared and packaged must be kept closed.

6. Natural or artificial ventilation must be appropriate for the capacity of the premises. Special attention must be paid to ventilation of areas and machinery that emit heat, steam or disagreeable vapours.

Air must circulate from the most hygienic to the least hygienic areas.

Plant openings, windows and vents must be fitted with mesh screens to prevent the entry of insects, birds or rodents.

Vessels must use appropriate systems for these purposes.

7. Natural or artificial illumination for the differenct areas and operations must comply with the following minimum standards:

Storage areas and passageways	50 LUX
Work areas demanding slight concentration, machine rooms, etc.	100 LUX
Work areas demanding close concentration or especially dangerous areas	200 LUX
Spot illumination for delicate operations (temperature control, etc.)	500 LUX

Lights and installations suspended over areas where fish is handled must be protected so that they will not contaminate food in the event of breakage.

8. Installations must always have potable running water or clean seawater available under pressure, in sufficient amounts for the preparation, handling and preparation of products. Ice used to preserve fish products must be made from potable water or clean seawater. Contamination is to be avoided during ice manufacture, handling and storage.

Water of lower quality may be used in steam generators, industrial refrigeration installations, fire-fighting systems and auxilliary services, provided that there is no connection between such systems and potable water systems. Non-potable water systems must be clearly identified. Clean seawater may be used to convey fish, clean it and prepare brine in accordance with industrial practises, provided it does not contaminate products.

9. Toilets and changing rooms must be provided in accordance with labour code regulations for each type of industry.

10. Handling and processing areas in plants and on vessels must be equipped with facilities for operators to wash and dry their hands and disinfect gloves, if necessary. Washbasins in these zones must have hot and cold running water. They must be activated by pedal or some other non-manual system. Hands are to be dried using disposable towels or automatic dryers.

11. In plants, wastewater is to be removed through a system equipped with collectors, sewers and pipes made of appropriate materials, that empties into a plant purification system or the public sewer system, provided that municipal permission is obtained.

12. In the event that the plants governed by these Regulations are not equipped with a system to destroy or transform waste from the manufacturing process, they must have separate waste storage areas, containing hygienic, incorrodable recipients or containers that can be easily cleaned and disinfected. The waste is to be removed daily and transported to plants for destruction or recycling.

13. Plants for the preparation of byproducts must be totally separate from those in which fish is prepared for human consumption and are subject to the Regulations governing unpleasant, unhealthy, noxious and dangerous activities.

14. Plants must be equipped with adequate devices and installations located in appropriate places to guarantee that products will be kept under optimum hygienic conditions and not be contaminated through proximity to or contact with any kind of waste, wastewater, smoke, dirt, foreign materials, insects, rodents or other animals.

They must maintain adequate environmental conditions so that the initial characteristics of the products will not experience abnormal changes, and systems must be provided to prevent sunlight from acting directly on the products.

15. Warehouses for finished products must be separate from areas in which products are handled, prepared and packaged.

16. Plants engaged in cutting up, filleting and packaging frozen and smoked fish products must keep the temperature in the rooms in which these operations are performed at not more than 16°C.

17. In vessels using cooled seawater or brine to preserve fish products, holds, heat exchangers, pumps and related conduits must be made of corrosion-resistant materials or lined with them.

18. All the plants subject to these Regulations are also subject to current regulations governing containers under pressure, high and low voltage electrical devices, plant safety, refrigeration devices, and in general, all other applicable industrial regulations depending on the nature of the plant.

19. The sole official weights and measures are those described in Weights and Measures Act 88/1967 of 8 November 1967 and Decree 1257/1974 of 25 April 1974 and the weighing and measuring devices used in manufacturing, distributing and selling the products governed by these Regulations must have been approved by the Office of the President of the Government and duly verified by the provincial offices of the Ministry of Industry and Energy, and if pertinent, by the corresponding services of the Regional Governments.

20. All companies that prepare fish products must provide their own laboratories or hire the services of a laboratory able to conduct

the regular tests of raw materials and finished products required for proper manufacture and compliance with these Reulations. Records of such tests must be kept for a minimum of three years.

21. In all industries using sterilization and metal capping processes, the persons in charge of these processes must furnish evidence that they are qualified to perform these operations.

Article 7 Work equipment and other devices

1. No machinery and other equipment that comes in contact with products during and after preparation and prior to packaging may transmit noxious properties to the products or cause changes in their organoleptic properties.

Surfaces must be impermeable, non-toxic, corrosion-resistant, and must allow for easy and thorough cleaning.

Unpackaged products must not be handled with any equipment or utensil made of wood, unless the wood is coated with an authorized material. If coveyor belts are used in preparation processes, they must be equipped with waste-removal devices and sprinklers when the circumstances warrant.

2. Containers used repeatedly in distribution must be made of suitable materials, be corrosion resistant, and constructed so they can be easily cleaned. They must have sufficient capacity to contain adequate amounts of ice and fish products and be shaped so they can be piled up after they are filled without damaging the contents in the lower containers. These containers may not be made of wood.

3. Non-recycleable containers must withstand necessary handling during distribution. If they are made of wood, they must be new and clean.

4. Containers meant to hold fish products during any kind of process must have drainage systems, except for those used for live crustaceans and mollusks prior to the start of the preservation process. The interior of wooden containers to hold cooked crustaceans must be lined with cellulose or another authorized lining.

5. Containers in which live mollusks are marketed must bear an unbroken seal, patterned on an official model, guaranteeing that they have not been tampered with and indicating that they come from a duly authorized depuration station. The competent departments are authorized to issue regulations governing how seals are to be applied.

Article 8 Cleaning, disinfection, insect and rodent extermination for premises, plants and utensils.

1. All premises must be kept clean, and cleaning is to be done using appropriate methods to prevent the raising of dust and pollutants. Factory floors and to be washed and disinfected when operating requirements so necessitate, and at least once a day on working days. Premises and installations must be disinfected, and insects and rodents must be exterminated as necessary.

2. After the end of each working day, or earlier if necessary, all tools, tanks, barrels, tables, containers, detachable parts of machines, knives, etc., that have come into contact with fish products must be thoroughly cleaned and disinfected.

Tools and machinery not in regular use must be washed and disinfected prior to each use.

3. Cleaning, disinfection, insect and rodent extermination in the establishments governed by these regulations must be done in such a way as to pose no risk of contaminating the fish, and the necessary products

must be properly applied and stored. Installations, apparatus and materials coming into direct contact with products for human consumption may only be treated with harmless cleaning materials or with special products or methods expressly and concretely authorized by the Under Secretary of Health and Consumer Affairs for this purpose.

Article 9 General conditions governing materials

All materials coming into contact with fresh, frozen, salted, brined, smoked, cooked, semi-preserved and canned products at any time during preparation, distribution or consumption, must be in good condition, clean, and comply with the following requirements in addition to all others specifically set out in these Regulations.

1. Be manufactured from authorized raw materials.
2. Not transmit toxic or contaminating substances to the products with which they come into contact.
   Not give off any substance foreign to the normal composition of fresh, frozen, salted, brined, dried, smoked, cooked, semi-preserved
   or canned fish products that exceeds tolerance limits.
3. Not alter the composition or the organoleptic characteristics of processed fish products.

Article 10 Specific conditions governing fishing vessels

1. Fishing vessels must be built to handle fish products rapidly, efficiently and hygienically, allow for easy cleaning and disinfection and be built from materials and in shapes that do not damage or contaminate fish products.

1.1 Holds for fish products must be thermally insulated.

Hold linings must be impermeable; insulation must be protected by a covering resistant to corrosion under normal working conditions. If the linings involve sheets of material, the joints must be watertight. If holds for fish products are made of wood, they must be kept in good condition or lined with a suitable material.

Holds must not have sharp or protruding edges that hamper cleaning or damage fish products.

Conduits for heat exchangers and pumps must not pass through them, except for conduits forming part of their cooling system.

1.2 Seawater and mixtures of brine and ice used to cool and store fish products must be clean and sufficient for the volume treated. If refrigerating equipment is required, it and the brine or seawater circulation equipment must be sufficient to maintain the temperature between 0°C and 5°C. If freezing equipment is used, it must be sufficient to store and maintain products at the temperature specified in Article 12 (3).

1.3 In addition to the general conditions set out in Article 6, the equipment used to wash and convey fish products must be easily disassembled for cleaning purposes and fitted with devices to carry the fish to the hold and drop them into it from heights of not more than one meter.

1.4 "Fish parks" and holds for storing fish products must be used for said purposes during fishing voyages.

1.5 Before the fish are brought on board, the "fish park" and all the equipment with which the fish will come into contact must be sluiced out with clean seawater to remove any dirt present.

1.6 All fishing vessels must have abundant supplies of potable water or clean seawater under pressure.

1.7 Ice used to preserve fish must have been made from potable water or clean seawater. Contamination of ice must be avoided during manufacture, handling and storage.

1.8 During fishing voyages, bilge must be frequently drained from the holds. Prior to storing the catch, the hold drains must be checked and properly cleaned.

1.9 Vessels that use bait for fishing must not allow it to contaminate the catch.

1.10 After the catch is unloaded, decks and all equipment must be washed down with hoses, scrubbed and carefully cleaned, and afterwards disinfected and rinced. Holds must be completely emptied and the same operations as required for decks repeated, and bilges must also be emptied and cleaned.

1.11 Food and packaged products for consumption by crews must be stored separately and not be permitted to come into contact with the catch.

2. Handling fish on board and conditions related thereto.

2.1 The length of a fishing voyage will depend on the capacity of the vessel to handle and maintain fresh fish on board and weather conditions in the fishing ground.

2.2 Vessels engaged in catching fresh fish during voyages longer than five days must make stowage plans.

2.3 Species not intended for human consumption are to be isolated from edible species and identified.

2.4 Bleeding and gutting must begin as soon as the catch is taken on board and after completion, the fish must be washed. If the fish cannot

be gutted immediately after they are caught, they must be washed with potable water or clean seawater as soon as they are taken aboard.

2.5 Fish kept in ice must be placed in thin layers and surrounded with sufficient quantities of ice. If placed in boxes, the boxes must not be overfilled and a layer of ice must be placed on top.

2.6 When fish are stored in seawater or cooled brine, not more than 350 grams of fish may be stored for each liter of liquid.

2.7 If ice is added to seawater or brine for storage, the concentration of salt may not be less than 3%.

2.8 Unloading, sorting, weighing and placing the catch in containers must be performed with care so that the fish will not be damaged or contaminated.

Article 11 Specific conditions for fresh fish processing plants

1. Fresh fish processing plants must comply with the conditions established in Article 6.

2. Fresh fish products must be handled, prepared and distributed as quickly as possible, and transported hygienically and sanitarily.

3. Plants must be capable of maintaining fresh fish products at proper temperatures.

4. Special priority will be given to encouraging the practise of preparing and packing fresh fish products on the vessels themselves while at sea.

Article 12 Specific conditions for frozen fish processing plants

1. Frozen fish processing plants must comply with the conditions established in Article 6.

2. They must be equipped with suitable freezing systems and storage areas tailored to treatment capacity. All must have graphic temperature-recording devices.

3. Temperatures in the centres of frozen fish products, once thermal stabilization is obtained, must be below:

Non-fatty, semi-fatty and fatty fish	-18°C
Crustaceans and mollusks	-16°C
Cephalopoda	-15°C
Tuna frozen in brine	- 9°C

4. Frozen fish products must be unloaded and transferred as quickly as possible to avoid unnecessary changes in temperature. During these operations, frozen products must be protected from weather phenomena that could affect their quality or temperature.

5. Glazing with potable water or clean seawater, with or without additives authorized by the Under Secretary of Health and Consumer Affairs, is permitted to protect products from oxidation and dissecation. The weight of the glaze must never be counted as part of the net weight.

6. Storage temperatures for frozen fish products must be adequate to maintain the temperatures listed in point 3, as a minimum.

7. Distribution temperatures for frozen fish products must be those listed in point 3 for the different species, as a minimum, with a tolerance of $\pm$ 3°C.

8. So that authorized technical procedures such as dismembering, brining, smoking, drying, canning, semi-preserving and partial or full cooking can be performed, the temperatures of frozen fish products may be raised to the minimum required to carry out these procedures, and once they are completed, products must be returned to the proper temperature, depending on the nature of the finished product, as quickly as possible.

9. Fish products may not be frozen in refrigerated chambers used for storage.

10. Frozen products may not be defrosted and sold as fresh or unthawed products, regardless of whether [the public] has been informed that the products were previously frozen.

Article 13 Specific conditions for dried, dried-salted, salted and/or brined fish plants

1. Plants must use suitable systems and, if necessary, whatever equipment is required to monitor the conditions under which the drying process is conducted, and comply with the necessary health requisites.

2. All products requiring whole, undamaged fish must be prepared at sea or on land as quickly as possible, and immediately stored and brined, always using new, table-quality common salt for this purpose.

3. Fish salted on board must be unloaded as quickly as possible, avoiding high temperatures and contact with water. Once on land, the layer of salt must be removed and the fish must be placed immediately afterwards in chambers or premises whose room temperature is not above 12°C, or stored in holding bins. They must then be dried in tunnels or on drying racks under adequate sanitary conditions.

Article 14 Specific conditions for smoked fish plants

1. Plants must be equipped with suitable ovens fitted with adequate systems to monitor and regulate the smoking process. If electronic smoking is used, it must be managed by experienced personnel, and temperatures, moisture and smoke density are to be regulated automatically.

2. Brine must be freshly prepared each day at the start of smoking activities. The ratio of brine to product must be at least 1:1 by mass when saturated brine is used.

3. Prior to smoking, the salt content in very salty fish products must be reduced through prolonged immersion in potable water. Immediately afterward, the products are to be hung on skewers or hooks or placed on trays for drying or smoking. Draining or drying of products prior to smoking must be performed hygienically under regulated conditions.

4. Fish products are to be smoked using procedures authorized by the Under Secretary of Health and Consumer Affairs.

5. During cold smoking, the temperature of the fish must be kept below the temperature at which the protein coagulates.

6. During hot smoking, the fish must be exposed for sufficient time to temperatures that completely coagulate the protein.

7. After smoking is completed, heated products must be cooled to room temperature prior to packaging.

Article 15 Specific conditions for fish cooking plants

1. Plants in which fish products are cooked must comply with the conditions set out in Article 6.

2. Mollusks with shells must be washed with potable water or clean sea-water prior to cooking.

3. Once mollusks are shelled, the waste must be quickly removed from the food preparation area.

4. Adequate ventilation must be installed to remove steam from the preparation area.

5. If cooked products are to be frozen, the plant must have suitable and sufficient equipment for freezing and storage until the products are sold.

Article 16 Specific conditions for fish canning plants

In addition to complying with the general conditions specified above, fish canning plants must comply with the following conditions, always in accordance with the applicable regulations issued by the Ministry of Industry and Energy.

1. Equipment for preliminary treatment and washing of fish products for canning.

2. Steam generator with sufficient capacity to feed autoclaves, cookers, etc.

3. Cooking apparatus.

4. Sealing machines or other capping devices. Before the containers are sealed, the appearance of the contents must be inspected. The sealing process and quality of the seals in each lot must be inspected as often as necessary to guarantee that the seals are hermetic.

5. Sterilization autoclaves with thermometers, manometers or the devices required to provide graphic data on time and temperature. If the autoclaves are equipped with purge systems, they must be easily accessible for inspection.

All newly-built plants and those that must purchase replacement autoclaves are required to use autoclaves equipped with systems to graphically record times and temperatures.

Records must be kept containing complete data on each sterilization process.

6. Plants must control the lots they manufacture and the codes and formulae used in the controls must be made available to the government unit responsible for health records.

7. Plants must also have a system for controlling finished products, for which purpose they must keep a control book in which data must be recorded on the following:

(1) Control of seals.

(2) Control of temperatures and times during the sterilization process.

(3) Control of lots manufactured.

(4) Results of chemical and microbiological tests.

The controls in question must be described in the control nook which must always be available for examination by government inspection services.

The page format for control books is given in Annex 2 of these Regulations.

Article 17 Specific conditions for plants that prepare semi-preserves

1. Equipment for preliminary treatment and washing of fish for semi-preserves.

2. Sealing machines or other capping devices. Before the containers are sealed, the appearance of the contents must be inspected. The sealing process and quality of the seals in each lot must be inspected as often as necessary to guarantee that the seals are hermetic.

3. Plants must control the lots they manufacture and the codes and formulae used in the controls must be made available to the government unit responsible for health records.

4. Plants must also have a system for controlling finished products, for which purpose they must keep a control book in which data must be recorded on the following:

(1) Control of container seals.

(2) Results of chemical and microbiological tests.

The controls in question must be described in the control book which must always be available for examination by government inspection services.

The page format for control books is given in Annex 2 of these Regulations.

Article 18 Specific conditions for mollusk depuration stations

1. In addition to the general conditions governing plants set out in Article 6, mollusk depuration stations must comply with the following requirements.

1.1 Bottoms and walls of depuration tanks and water tanks must be smooth, hard, impermeable, resistant and easy to clean. The bottoms of depuration tanks must have a minimum grade of 2% and drains with sufficient capacity for the volume of work.

1.2 A receipt and prewashing zone, where mussels are washed with clean seawater prior to depuration.

1.3 The minimum seawater flow to mollusk depuration tanks must be 15 cubic meters per hour and ton of mollusks placed in them.

1.4 Intakes for seawater to be used in cleansing mollusks must be located at a minimum of 2.5 meters below the low water line.

1.5 No drains, sewers or emissions that could contaminate the seawater may be present in zones from which seawater is taken for use in depuration tanks.

1.6 The maximum mass of mollusks to be treated per square meter of depuration tank surface is 30 kilograms. Any private or corporate person who operates depuration tanks and who believes that the system he uses permits the limit of 30 kilograms per square meter to be exceeded may apply to the Under Secretary of Health and Consumer Affairs for permission to surpass the limit. In no event may the maximum mass of mollusks exceed 45 kilograms per square meter.

1.7 The distance between water intakes and outlets for wastewater produced in cleansing mollusks projected on a straight line parallel to the coast, may never be less than 250 meters and the operation is not to be performed in zones where sewage is discharged or in zones close to known sources of pollution.

1.8 Water from mollusk depuration tanks must be put through a plant purification system prior to its discharge into the sea.

1.9 The daily capacity of a mollusk depuration cleaning station is determined by the following formula:

$$\text{Daily depuration capacity in kilograms} \quad \frac{A \times B}{2}$$

Where A = square meters of depuration tank

B = authorized load in kilograms

1.10 Mollusks must be subject to continuous depuration for a minimum of 42 hours.

The time is to be counted from the moment at which the depuration tank is filled to capacity with water until it is drained. Plants must take into account the condition of the raw material (type of mollusk, zone of origin, microbial load, etc.) to determine whether it is necessary to increase the depuration period to guarantee public health.

1.11 Mollusks are to be depurated on trays or in bulk on plastic mesh. Depuration in sacs, regardless of their capacity, is prohibited.

1.12 Seawater must be sterilized using systems authorized by the Under Secretary of Health and Consumer Affairs.

1.13 Mollusk depuration stations must have laboratories properly equipped to conduct the tests required by law.

1.14 Microbiological specifications and specifications for other contaminants for the purpose of judging when a mollusk is depurated will be established in a resolution issued by the Under Secretary of Health and Consumer Affairs. The tests to be performed must be conducted following the methods established by the Under Secretary of Health and Consumer Affairs, upon receipt of an assenting report from the Inter-Ministerial Food Regulatory Committee.

1.15 Mollusk depuration stations must keep the following records:

(a) Water analyses

(b) Mollusk analyses

(c) Control of labelling and depuration.

The models for the record books are given in Annex 3 of these Regulations.

Data are to be entered daily in the books during the time that each depuration station is in operation.

Article 19 Specific conditions for crab cleaning and handling centres

In addition to the general conditions set out in Article 6, these installations must have the following:

(1) Water tanks for cleaning the crustaceans.

(2) The bottoms and walls of the tanks must be smooth, hard, impermeable, resistant and easy to clean, with sufficient drainage capacity for the volume of work.

(3) The water used in the tanks must be potable and the supply must be continuous.

Article 20 Specific conditions for fish farms

All fish farms that sell products for human consumtion must have an area for slaughter, handling and packaging.

The area must comply with the general conditions set out in Article 6.

The competent government departments will establish the criteria governing slaughtering systems and postmortem health inspection for the fish processed in these stations.

If fish are frozen at fish farms, the installations must have the necessary freezing systems and storage areas.

Article 21 Conditions governing personnel

1. Personnel engaged in handling, preparing or distributing fresh, frozen, salted, brined, dried, smoked, cooked, semi-preserved or canned fish products must maintain strict personal hygiene at all times and use clean protective work clothing, head coverings and footwear suited to the work. They may not wear work clothes except when they are working.

2. Every person who handles, treats or packs fish products must wash his hands with water and soap or similar products as often as is required by work conditions, and always prior to starting work after an absence from the work station.

3. It is forbidden to smoke, eat, chew gum or tobacco or engage in any other unhygienic practice in areas in which fish products are prepared, packed or handled.

4. Persons suffering from contageous diseases or carriers of harmful germs may not engage in handling fish products.

Without prejudice to this Article, personnel will be regulated in general terms under the provisions of Royal Decree 2905/1983 of 4 August 1983 in respect of food handlers.

CHAPTER III

General Health Register

Article 22 Identification of plants

Plants engaged in the activities governed by these Health Regulations must register in the General Food Health Register, in accordance with the provisions of Royal Decree 2825/1981 of 27 November 1981 (Official Gazette of December 2), without prejudice to inscription in the other registers required under current legislation.

CHAPTER IV

Raw materials and typical ingredients in finished products

Article 23 Raw materials and other ingredients

1. In preparing frozen, salted, brined, smoked, dried, cooked, canned and semi-preserved products the basic raw materials to be used are freshwater and saltwater fish, crustaceans, mollusks, mammals and other edible animals.

2. The remaining raw materials and ingredients include water, edible fats, derivatives of leguminosae, eggs, garden vegetables, milk and dairy products, flour and flour byproducts, sugar derivatives, condiments and spices, aromatic agents and additives authorized by the Under Secretary of Health and Consumer Affairs. This list of ingredients is not intended to be exhaustive.

3. All the materials used in establishments engaged in preparing fish products must comply with the health requirements for quality and purity contained in the specific legislation regulating such matters.

4. Raw materials, ingredients and additives are to be received in places designated as receiving zones.

5. Manufacturers must control raw materials and other ingredients, verifying their sanitary condition and aptness for human consumption at the time of receipt or use, through appropriate examinations and tests or through quality certificates from suppliers.

6. Fresh fish products, in addition to being used for direct consumption, always form the basis for prepared fish products. Given their importance, whole fresh fish must comply with all the requisite organoleptic, health and hygiene characteristics. The following health-hygiene categories are based on organoleptic characteristics.

6.1 Fish

Extra grade. Fish from inshore fisheries, shellfisheries or fish farms, live or dead, that normally reach their first point of sale without the need to use ice, salt or other preservatives.

Products in this grade are defined by the following characteristics:

1. External appearance:

   Very bright colours.

   Transparent cutaneous mucus.

2. Eyes:

   Convex eyeball.

   Transparent cornea.

   Bright black pupil.

3. Gills:

Bright red colour, odourless or with characteristic odour.

Filaments perfectly separated, long, uniformly alligned.

4. Consistency:

Rigid body or signs of partial disappearance of rigidity.

5. Abdominal cavity:

Spots of bright red blood.

Clear serous membrane.

Grade A Products in this grade are defined by the following characteristics.

1. External appearance:

Insignificant loss of pigmentation.

Major loss of pigmentation due to mechanical factors [sic]

Slightly cloudy mucus.

2. Eyes:

Convex eyeball, slightly sunken.

Slightly opalescent cornea.

Cloudy black pupil.

3. Gills:

Less red (pink), odourless.

Filaments stuck together in groups.

4. Consistency:

Firm, elastic, pressure marks disappear immediately and completely.

5. Abdominal cavity:

Medium red blood spots.

Clear serous membrane.

Grade B The products belonging to this grade are defined by the following characteristics.

1. External appearance:

   Slight lesions.

   Pigmentation becoming discoloured and loss of shine.

   Opaque mucus.

2. Eyes:

   Flat eyeball.

   Opalescent cornea.

   Opaque pupil.

3. Gills:

   Somewhat pale and stuck together.

   "Fishy" smell.

   Filaments stuck in groups and of different lengths.

4. Consistency:

   Mechanical marks present.

   Elasticity noticeably reduced, slight body deformation.

5. Abdominal cavity:

   Traces of reddish-brown blood.

   Cloudy serous membrane.

Grade C. The products belonging to this grade are defined by the following characteristics.

1. External appearance:

   Little shine on the surface.

   Loss of pigmentataion.

   Major body lesions.

   Yellowish mucus and dry skin.

2. Eyes:

Concave, milky cornea, ill-defined internal parts.

3. Gills:

Dirty greyish-yellow colour, dry grainy appearance, intense smell of ammonia.

Filaments totally stuck together, partly detached and noticeably shortened.

4. Consistency:

Major changes in the typical shape of the fish due to mechanical damage.

5. Abdominal cavity:

Visible blood spots, dirty in colour.

Abundant mucus, serous membrane with continuous solution.

6.2 Crustaceans

Extra grade From inshore fishing, fish farms or hatcheries, live, and exhibiting reflex actions in the eyes, antennae and claws.

Grade A. Caught on the high sea and generally preserved in ice. They must have the following organoleptic characteristics.

1. Black, firm, shiny eyes.
2. Firm musculature.
3. Resistant, shiny and clear thoracic-abdominal membrane.
4. Odour agreeable or absent.
5. Virtual absence of melanosis.

Grade C Products in this grade are defined by the following characteristics.

1. Discoloured, soft, wrinkled eyes.
2. Slack musculature.

3. Thoracic-abdominal membrane slack, soft, greenish or blackish.

4. Putrid smell at mouth level.

5. Marked melanosis.

(Note the absence of Grade B in crustaceans).

6.3 Mollusks

Bivalves and Gasteropoda

Extra grade (sole grade) The mollusks belonging to this grade must be sold live to the consumer.

If they can be eaten raw, they must also be depurated in accordance with the provisions governing this matter.

Cephalopoda

Extra grade The products belonging to this grade are defined according to the following organoleptic characteristics.

1. External appearance:

Bright pigmentation with intact chromatophora.

Skin smooth, soft and intact.

Typical colour for the species.

2. Odour:

Agreeable or absent.

3. Flesh:

White, firm, pearly.

4. In Decapoda, the tentacles firmly joined to the mantle.

Grade A. Products in this grade are defined by the following organoleptic characteristics.

1. External appearance.

Marked pigmentation, with the chromotophora easily distinguished.

Skin smooth, soft, with minor continuous solutions.

Typical colour for the species, with a tendency to darken.

2. Odour:

Of shellfish, not disagreeable.

3. Flesh:

Firm, dull white.

4. For Decapoda, the tentacles firmly attached to the mantle.

Grade B The products in this grade are defined by the following organoleptic characteristics.

1. External appearance:

Natural pigmentation practically gone.

Skin highly deteriorated, mostly missing.

Violet colour.

2. Odour:

Strong and clearly disagreeable.

3. Flesh:

Poor consistency, violet-yellow to purple.

4. For Decapoda, tentacles unconnected to the mantle.

(Note the absence of grade C for mollusks).

6.4 Grade D (for all species) Fish products having one of the following characteristics:

1. High level of radioactivity.
2. High content of certain heavy metals.
3. Presence of pathogens dangerous to humans and animals.
4. High chemical content or active signs of highly toxic agents or agents the modify the organoleptic characteristics defined for grade C.

7. Use of products.

In accordance with the health categories described in paragraphs 6.1, 6.2, 6.3 and 6.4, the following uses are established for each of the grades:

Grade extra: all

Grade A: all

Grade B: with the following restrictions on use:

1. May not be frozen.
2. When the product exhibits each and every one of the characteristics for this grade, it may only be sold on the local market at the port of origin.

Grade C: may be used only for animal consumption, directly or after reduction, hydrolysis, processing, etc., and/or for agricultural uses.

Grade D: not apt for animal consumption. Must be incinerated.

For canning purposes, lots from the first three grades, except for cephalopods, may occasionally show signs of certain mechanical or physical damage, loss of skin, shells or exoskeletons, depending on the case, provided their consistency and organoleptic characteristics are typical of the species and correspond to the pertinent quality standards.

Article 24 Microbiological standards

Microbiological standards, biochemical specifications and heavy metal tolerances for all fish products will be set, after receipt of an assenting report from the Inter-Ministerial Food Regulatory Committee, by the Under Secretary of Health and Consumer affairs, after hearing the opinion of the sectors affected.

Article 25. Characteristics of finished products

1. Fish products may be placed on sale to the public, whole or in typical cuts, gutted, headed, headed and gutted, dismembered, split scaled, skinned, shelled, filleted, as cakes, ground or homogenized. Edible viscera such as roe, liver, etc., are also included.

Products may be presented naturally, glazed, covered with liquid or mixed with any of the ingredients mentioned in Article 23 (2), provided they have been declared in the Register referred to in Article 22 of these Regulations.

2. The proportions of ingredients will be defined by specific quality standards, if any, technological requirements, good manufacturing practises, product quality requirements and any applicable restrictions issued by the authorities competent to act in each case.

3. Finished products must not contain microorganisms, pathogenic parasites or substances produced by them in concentrations that pose a threat to health, or toxic substances that may pose a risk to consumers. This same criterion will apply to other substances, which while not toxic, unfavourably alter organoleptic characteristics and can cause consumers to feel repugnance.

4. Fish products may not contain trace metals in excess of the tolerances set for them by resolution of the Under Secretary of Health and Consumer Affairs, contingent on an assenting report from the Inter-Ministerial Food Regulatory Committee.

5. Fresh fish products. Must have the characteristics defined in Article 23 (6.1) (6.2) and (6.3), and Article 23 (7) is to be taken into account with regard to the purposes for which they can be used.

6. Frozen fish products.

6.1 Frozen fish products, when cut up, must be compact in appearance and no ice crystals may be visible to the naked eye.

During unthawing, they must not exude much liquid, and once thawed, they must have the appearance, consistency and smell of fresh products, and show no signs of rancidity or refreezing.

6.2 Except for round fish, all other cuts must be gutted, and in the case of cephalopods, the endoskeleton must be removed.

6.3 For technical reasons, fish cakes, minced and homogenized frozen fish products may contain mixtures of certain non-fish ingredients that act as fillers. The maximum proportions will be defined in specific standards.

6.4 Health quality is as defined as in sections 6.1, 6.2 and 6.3 governing fresh fish.

6.5 Mollusks that can be eaten raw and which therefore must compulsorily be depurated must be frozen in authorized plants and within the deadline appearing on the depuration control tag that must accompany the product at all times.

Plants that freeze mollusks must keep quality controls showing the date of freezing and the full dates appearing on the depuration control tags and on the official seals or fastenings.

7. Salted and brined fish products. Finished products must have the following characteristics: the special aroma, colour and flavour obtained by salting, pressing and curing. The minimum sodium chloride content in the mass is 12%.

These products must be firm to the touch, taste salty and have a typical colour, depending on the species and the preparation method.

8. Smoked fish products. Smoked fish products must be consistent to the touch, and not present abnormal spots, smells, colours or tastes. They must not emit water when pressed by the fingers. In finished products, the formaldehyde content must not be above 200 ppm.

Reddish or greenish spots that affect the product are not permitted in smoked fish products and they must not be affected by fungi.

9. Dried fish products. The moisture limit for these products is 15% maximum. The presence of reddish or greenish spots that affect the product are not permitted and no fungus spots may be present.

10. Dried salted fish products. Must present the aroma and flavour characteristic of the product. The moisture content must be between 30% and 50% and the salt content below 25%. They must not present abnormal odours or flavours, coagulated blood, insects, fungi or mites.

11. Cooked fish products. They must be free from pathogenic flora and noxious products manufactured by flora.

12. Semi-preserves. In addition to the general standards, these products must comply with the following requirements:

12.1 The containers must not exhibit convex bulges.

12.2 The containers must be impermeable to water under normal pressure.

12.3 The contents must retain the organoleptic characteristics of the species and ingredients used.

13. Canned fish products. In addition to the general standards, these products must comply with the followng requirements:

13.1 The cans must not exhibit convex bulges.

13.2 The containers must be hermetic. They must therefore not leak through the seams, soldered joints or other surfaces.

13.3 The contents must retain the organoleptic characteristics typical of the species and ingredients used.

13.4 For control of sterilization systems the canning plant must submit as many samples of each lot as are required for incubation tests, in accordance with the methods recommended by the Under Secretary of Health and Consumer Affairs.

Article 26

The products in the generic groups covered by these Regulations will be subject to specific quality standards that supplement the general specifications.

Article 27. List of additives

The following stipulations with regard to additives and their specifications for them have been approved by the Under Secretary of Health and Consumer Affairs of the Ministry of Health and Consumer Affairs.

In accordance with Article 2.2 of Decree 2919/1974 of 9 August 1974, the Under Secretary may change the list of additives at any time by issuing a Resolution.

The following additives must comply with the standards governing identification, quality and purity set by the Under Secretary of Health and Consumer Affairs of the Ministry of Health and Consumer Affairs.*

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*List of additives not submitted for translation. Tr.